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## **SUMMARY OF SAFETY AND EFFECTIVENESS VALLEYLAB COATED ELECTRODES**

### Intended Use

Valleylab Coated Electrodes are intended as an alternative to uncoated stainless steel electrodes or "non-stick" coated electrodes for use in conventional monopolar electrosurgical accessories. The Coated Electrodes are intended for use in situations where monopolar electrosurgical cutting and coagulation are normally used.

### Product Description

The Valleylab Coated Electrodes are modifications of Valleylab's line of single-use electrodes that includes various tip configurations. The coating provides a non-stick surface for easier cleaning of eschar during electrosurgery.

The electrodes are intended for use with monopolar electrosurgical accessories, and will be packaged separately as well as in combination with Valleylab electrosurgical pencils. The Coated Electrodes will also fit in currently marketed electrosurgical pencils offered by other manufacturers.

### Safety and Performance

#### **1. Biocompatibility Testing**

The biological safety of the Valleylab Coated Electrodes has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. The components of the Coated Electrodes have incidental short term contact with patient tissues at the surgical site.

#### **2. Performance Testing**

Performance testing was performed on prototype Valleylab Coated Electrodes (blade configuration). This configuration is representative of the range of electrodes which will be available in a coated form.

#### Electrode Cleanability and Durability

The Valleylab Coated Blade Electrode retained its easy to clean properties for a longer period of use than other coated electrodes or standard uncoated stainless steel electrodes tested.

#### Electrode Cut Performance

The Valleylab Coated Blade Electrode initiates cutting immediately and continues to cut more readily and consistently than "non-stick" coated blades at both lower and higher power settings.

#### Electrode Bendability Test

The Valleylab Coated Blade Electrode was bent to a maximum of 90 degrees ten times or until failure of the steel blade, without visible cracking of the coating.

#### Pre-Clinical Performance

In pre-clinical trials involving a variety of surgical procedures in swine, surgeons rated the performance of the Valleylab Coated Blade equal or superior to other coated blades tested.